UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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ROBERT JONES and KRISTA JONES,

Plaintiffs,

Civil Action No.: 08 CV 2060 (JAP)

-against-

SYNTHES USA SALES, LLC, SYNTHES USA PRODUCTS, LLC, JOHN DOES 1-5, and ABC CORP. 1-5,

Defendants.

DOCUMENT ELECTRONICALLY FILED

Motion Date: May 3, 2010

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DEFENDANTS SYNTHES USA SALES, LLC AND SYNTHES USA PRODUCTS, LLC'S RESPONSE TO PLAINTIFF'S SUPPLEMENTAL STATEMENT OF MATERIAL FACTS

Pursuant to L.Civ.R 56.1(a) defendants, SYNTHES USA SALES, LLC and SYNTHES USA PRODUCTS, LLC, by their attorneys, Sedgwick, Detert, Moran & Arnold LLP, respectfully submit the following response to Plaintiff's Supplemental Statement of Material Facts:

1. Admitted that the testimony is accurately characterized but with the qualification that plaintiff reported the onset of lower back and extremity symptoms, pain, discomfort and numbness and tingling on several occasions (September 28, 2005, October 24, 2005, December 5, 2005, February 9, 2006, April 13, 2006 and April 18, 2006) after the initial surgery, during the time period when diagnostic films showed the instrumentation including the ATB screws to be intact and before he reported allegedly feeling a "pop" in his back. See SYNTH000238-239, SYNTH000245, SYNTH000247-248 at Ex. P.

2. Denied. The paragraph does not accurately describe Dr. Levine's testimony or reference his prior testimony that he could not specifically identify when the ATB screw broke or make a dot to dot determination that plaintiff's feeling of a "pop" can be directly attributed to the breakage of the ATB screws. See Levine Dep., p. 156-157 at Ex. R.

3. Admitted that the testimony is quoted accurately but denies plaintiff's implication that Dr. Levine opined that a time range for fusion is six months to two years. The quoted testimony does not support said implication. Dr.

Levine testified that he does not start physical therapy until three months "to let the fusion get an opportunity to get off…" This implies fusion can start at three months in certain patients not six months. Moreover, Dr. Levine testified that the time frame for fusion varies. Dr. Levine also testified that "not all fusions fuse" and that "there's certainly a rate of non-fusion in the spine as well as elsewhere in the body for all orthopedic procedures. A fracture, the fracture doesn't always have fusion and you get a malunion, and the same thing occurs when you do a fusion of the spine, you can get a non-solid fusion." Levine Dep., p. 55-56 at Ex. R.

4. Admitted that the testimony is accurately quoted. Deny any implication that plaintiff's current complaints are related to the breakage of the ATB screws. Levine Dep., p. 79, 92-93 at Ex. R.

5. Admitted that the quote is accurately written but deny any implication that this proves that solid fusion had occurred. Plaintiff failed to include a 6/19/06 addendum to the note that was requested by Dr. Levine. The addendum states "There is some increased density within the disc space which may reflect partial post-surgical ossification. I cannot clearly demonstrate bony bridging anteriorly however this area is somewhat difficult to evaluate related to beam hardening artifact from the metallic fixation plate anteriorly." SYNTH000388 at Ex. P. Dr. Levine testified that this was a fancy way of saying that it could not be determined if fusion was occurring because the plate blocked

the scan. Levine Dep., p. 194-195 at Ex. R. Dr. Levine further testified that he did not believe fusion had occurred because "I think in general when you have broken hardware you have to at least believe there is a high incidence that a fusion is not solid, which would allow the ongoing micromotion that could possibly fail a piece of hardware." Levine Dep., p. 90 at Ex. R. Dr. Spielman also opined by affidavit that there is no firm evidence that plaintiff ever achieved partial fusion. Spielman Aff. ¶ 16 at Ex. H.

6. Denied. The second surgery was necessitated by plaintiff's failure to achieve fusion not by breakage of the ATB screws. See Levine Dep., p. 79, 90, 92-94 at Ex. R; SYNTH000232-000236 (showing the instrumentation remained in place despite screw breakage); Spielman Aff. ¶ 4, 6, 8, 11, 13, 15-16 at Ex. H.

7. Admitted.

8. Admitted.

9. Admitted.

10. Admitted.

11. Admitted.

12. Denied. Synthes manufactures other categories of screws beyond pedicle screws and screws used to affix plate to bone.

13. Denied as stated. The ATB Technique Guide provides full indications of use of ATB. See Ex. M at SYNTH001893.

14. Denied to the extent of plaintiff's use of the term "other products." The 5.5 millimeter titanium cancellous locking screws at issue in this lawsuit are only used with the Synthes ATB and Synthes Thoracolumbar Spine Locking Plate.

15. Admitted only to the extent that the ATB was not tested to dynamic failure but that the ATB including the screws did undergo dynamic compression/bending tests utilizing the Benynnon test method. See Ex. O at SYNTH001701 – SYNTH001703.

16. Admitted only to the extent that the ATB was not tested to cyclical failure but that the ATB including the screws did undergo dynamic compression bending tests utilizing the Benynnon test method. See Ex. O at SYNTH001701 – SYNTH001703.

17. Denied as stated. The ATB construct (plate and screws) was tested to failure during single cycle axial compression tests. See Ex. O at SYNTH001701 – SYNTH001703.

18. Admitted that no computer testing was performed but deny the implication that said testing was necessary. Synthes performed testing in accordance with industry standards and provided said testing to the FDA as part of the 510(k) submission. See Ex. O at SYNTH001701 – SYNTH001703.

19. Denied. The Synthes ATB underwent dynamic compression bending tests where tension and compression are applied to the device. See Ex. O at SYNTH001701 – SYNTH001703.

20. Admitted that the testimony is accurately quoted.

21. Admitted that the testimony is accurately quoted but with the qualification that fusion does not occur in all patients. See Synthes Response No. 3.

22. Admitted that no such calculations were performed but deny the implication that it was possible for Synthes to calculate a range of cycles it would be "expected to experience once installed in a typical fusion patient." As stated by Dr. Lyle Zardiackas:

> This process of multiple loading is termed fatigue. The process of fatigue is not dependent upon time but rather the number of cycles and the load applied during each of those loading cycles. This phenomenon of variable loading during each cycle is termed a 'variable load spectrum'. This type of loading is especially true for the motion of the human body. It is well recognized in the field of Biomedical Materials Science that, since each patient's physiology, activity level, and activity type is different, a complete evaluation of any fixation device is not possible. This situation does not occur for other types of devices such as airplane wings, automobile suspensions or bridges where testing and/or calculations to determine fatigue life are possible and routinely done. Accordingly, there have been no tests developed by ASTM International or any other agency for determining the in vivo fatigue life of orthopaedic fixation implants.
>
> …It is also not possible to determine how long a device designed for this type of application will last either as a function of time or as a number of cycles because the load for each cycle imposed on the

> implant by an individual cannot be determined. The reason for this dilemma is that no two patients have the same anatomy or physiology, nor do they impose the same variable load spectrum on a device which has been implanted.

See Zardiackas Aff. ¶ 6 at Ex. I.

23. Denied as stated. The testing referred to in the paragraph was the only mechanical testing submitted to the FDA as part of the 510(k) submission. See Ex. O.

24. Admitted but Synthes refers the Court to SYNTH001701 – SYNTH001703 at Ex. O for a full description of the tests.

25. Admitted but Synthes refers the Court to SYNTH001701 – SYNTH001703 at Ex. O for a full description of the tests.

26. Admitted.

27. Denied as stated. Synthes incorporates its response to number 22.

28. Admitted.

29. Admitted but denies the implication that others were not consulted in the design of the ATB or that Synthes' prior experience with internal fixation devices and orthopedic surgery did not also play a role in the design.

30. Admitted but denies the implication that others were not consulted in the design of the ATB or that Synthes' prior experience with internal fixation devices and orthopedic surgery did not also play a role in the design.

31. Admitted only to the extent that the FDA did determine that the ATB was a substantially equivalent device. Denied that the ATB was not tested and the implication that it was possible for Synthes to create a test "to recreate all of the expected forces introduced during the fusion healing process…" As stated by Dr. Lyle Zardiackas:

> This process of multiple loading is termed fatigue. The process of fatigue is not dependent upon time but rather the number of cycles and the load applied during each of those loading cycles. This phenomenon of variable loading during each cycle is termed a 'variable load spectrum'. This type of loading is especially true for the motion of the human body. It is well recognized in the field of Biomedical Materials Science that, since each patient's physiology, activity level, and activity type is different, a complete evaluation of any fixation device is not possible. This situation does not occur for other types of devices such as airplane wings, automobile suspensions or bridges where testing and/or calculations to determine fatigue life are possible and routinely done. Accordingly, there have been no tests developed by ASTM International or any other agency for determining the in vivo fatigue life of orthopaedic fixation implants.
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> …It is also not possible to determine how long a device designed for this type of application will last either as a function of time or as a number of cycles because the load for each cycle imposed on the implant by an individual cannot be determined. The reason for this dilemma is that no two patients have the same anatomy or physiology, nor do they impose the same variable load spectrum on a device which has been implanted.
>
> See Zardiackas Aff. ¶ 6-7 at Ex. I.

32. Admitted.

33. Denied as stated and because the quote is taken out of context. Dr. Zardiackas' opinion on the issue of shot peening needs to be read in whole to provide context.

34. Denied as stated and because the quote is taken out of context. Dr. Zardiackas' opinion on the issue of shot peening needs to be read in whole to provide context.

Dated: April 9, 2010

SEDGWICK, DETERT, MORAN & ARNOLD LLP

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PROOF OF MAILING AND CERTIFICATE OF SERVICE

DOCUMENT ELECTRONICALLY FILED

I, BARRY GERSTMAN, hereby certify and affirm that a true and correct copy of the attached DEFENDANTS SYNTHES USA SALES, LLC AND SYNTHES USA PRODUCTS, LLC'S RESPONSE TO PLAINTIFF'S SUPPLEMENTAL STATEMENT OF MATERIAL FACTS was served via regular mail and electronically on this 9th day of April, 2010, upon the following:

White & Williams LLP
Attorneys for Plaintiffs
LibertyView
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s/Barry Gerstman
BARRY L. GERSTMAN (BLG-3691)